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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 687,593	10/13/2000	Osamu Tetsu	M-9005 US	9434

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EXAMINER

LOEB, BRONWEN

ART UNIT PAPER NUMBER

1636

DATE MAILED: 09/09/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/687,593

Applicant(s)

TETSU ET AL.

Examiner

Bronwen M. Loeb

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-21 and 94 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-21 and 94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on 11 June 2002 is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Copy of Papers Originally Filed.

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The following papers have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process:

Mailroom Stamp Date

Certificate of Mailing Date

11 June 2002

4 June 2002

Pages <sup>\*</sup>10 + 11

The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

COPY OF PAPERS  
ORIGINALLY FILED

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will, **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

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### **DETAILED ACTION**

This action is in response to the amendment filed 11 June 2002 in which claims 1, 7, 10 and 19 were amended, new claim 94 was presented and claims 22-93 were cancelled.

Claims 1-21 and 94 are pending.

### ***Drawings***

1. The corrected or substitute drawings were received on 11 June 2002. These drawings are acceptable.

### ***Response to Amendment***

2. The rejection of claims 7, 10 and 19 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of Applicant's amendment.
3. Claim 21 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reasons of record and as further discussed below.

Claims 1, 2, 6, and 10-12, and new claim 94, stand rejected under 35 U.S.C. 102(e) as being anticipated by Karin et al (USP 6,242,253) for reasons of record and as further discussed below.

Claims 1-12 and 19-21, and new claim 94, stand rejected under 35 U.S.C. 103(a) as being unpatentable over Karin et al as applied to claims 1, 2, 6, and 10-12, and new claim 94, and further in view of Sadowski et al (USP 5,885,779), Young (Biology of

Reproduction (1998) 58:302-311) and Finley et al (in The Yeast Two-Hybrid System, eds. P. Bartel, S. Fields, Oxford University Press, (1997) pp. 197-214).

Claims 1-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al (USP 5,851,775), in view of Sadowski et al, Young, Finley et al, Hagahara et al (Nature Medicine (1998) 4:1449-1452) and Schwarze et al (Science (1999) 285:1569-1572).

4. New grounds of rejection, necessitated by Applicant's amendment, are presented below.

#### ***Response to Arguments***

5. With regard to the rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being indefinite, Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that the amendment to claim 1 to recite "a first nucleic acid" overcomes this rejection. This is not persuasive. As stated in the previous action, it is unclear what the nexus is between the second nucleic acid (which encodes only the ligand or metabolic product and not the chimeric protein comprising the ligand or metabolic product) and the other steps of the method. Is this second nucleic acid to over express the ligand or metabolic product to compete with the chimeric protein for binding to the other chimeric protein?

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6. With regard to the rejection of claims 1, 2, 6, and 10-12, and new claim 94, under 35 U.S.C. 102(e) as being anticipated by Karin et al (USP 6,242,253), Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that Karin et al does not teach screening for an agent that modulates the ability of a cell to accumulate or to degrade a metabolic product but rather teaches screening for agents that alter the association between I $\kappa$ B kinase (IKK) and a protein that binds to IKK. This argument is not persuasive for several reasons. The actual steps in the pending claim are identical to those taught in Karin et al. It is assumed therefore that the same goal will be achieved. This assumption is supported by Applicant's specification. For instance, p. 15, the first full paragraph teaches that when no complex is formed between the two hybrid proteins, then there is no signal from the effector gene. This phenotype is precisely what would be observed for an agent that alters the association between the two hybrid proteins such that they cannot interact. See for instance col. 25, lines 51-53 Karin et al. Furthermore, if an agent inhibits the kinase activity of IKK, then the metabolic product that would accumulate would be, for instance, unphosphorylated I $\kappa$ B. Thus, the teachings of Karin et al inherently teach the accumulation or degradation of a metabolic product as a result of screening for an agent that alters the association between the two hybrid proteins. Therefore, Karin et al anticipates the claims and the rejection is maintained.

7. With regard to the rejection of claims 1-12 and 19-21 and new claim 94 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Karin et al as applied to

claims 1, 2, 6, and 10-12 and new claim 94 and further in view of Sadowski et al, Young and Finley et al.

Applicant argues that Karin et al is a defective reference and that none of Sadowski et al, Young and Finley et al make up for this deficiency. As discussed above, however, Karin et al is not a deficient reference. The other references were cited to demonstrate elements well known for use in two-hybrid assays that are recited in the pending claims. Thus, the argument is not persuasive and the rejection is maintained.

8. With regard to the rejection of claims 1-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al, in view of Sadowski et al, Young, Finley et al, Hagahara et al and Schwarze et al.

Applicant argues that Barker et al is deficient in that Barker et al does not teach screening for an agent that modulates the ability of a cell to accumulate or to degrade a metabolic product. This argument is not persuasive for the same reasons that this argument against the Karin et al reference was not persuasive. Specifically, an agent that inhibits the binding of  $\beta$ -catenin and Tcf-4 in a two-hybrid assay will have the same phenotype as an agent screened in Applicant's method: there is no signal from the effector gene (if transcription results only when the hybrids interact). An agent identified in the method of Barker et al as inhibiting the binding of  $\beta$ -catenin and Tcf-4 would be expected to permit the accumulation of  $\beta$ -catenin. The other references were cited to demonstrate elements well known for use in two-hybrid assays that are recited



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in the pending claims. Thus, the argument is not persuasive and the rejection is maintained.

**New Grounds of Rejection**

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 94 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 94 is vague and indefinite in reciting "said metabolic product is a metabolic product that is accumulated by said cell". It is unclear if the metabolic product accumulates with respect to the presence or the absence of the agent being screened in the method of claim 1.

***Conclusion***

Claims 1-21 and 94 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Bronwen M. Loeb, Ph.D.  
Patent Examiner  
Art Unit 1636

September 9, 2002

  
REMY YUCEL, PH.D  
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